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The present invention, which is a joint invention of Mr. Jacques CALZIA and Mr. Alain GRANGER, concerns a permanent autostatic catheter which is used more specifically for draining urine from the bladder.

In the description that follows, the term "permanent catheter" means a catheter that remains in place for a sufficiently long time, from several hours to several months, and the term "autostatic" means that the catheter is self-retaining, for example, by means of an adhesive tape or a collar that can be sutured.

Normally catheters that are used as permanent devices in the bladder (Figure 1) have at their distal end a small balloon (32), which has to be inflated after placing the catheter. The balloon is supported by the inside surface of the bladder (33) and prevents the catheter from being prematurely retracted. The disadvantage of these catheters resides in the fact that with this position of ports (30) between the distal (35) and the balloon (32) the draining of the bladder is incomplete, whereby stagnant urine (36) remains in the bladder, which often causes incrustation of the outer wall of the balloon, and the catheter should be replaced frequently. In addition, the balloon catheters are inconvenient because they require the use of auxiliary devices for inflating the balloon, and their fabrication is complex because it is difficult to make the balloon that is both airtight and delicate. Moreover, the balloon capacity must be known precisely in order to avoid the risk of its burst during inflation, which would result in entry of an undesirable fluid into the cavity being drained.

Catheters may also have in the non-use condition an enlargement at the distal end such as in Malécot or Pezzer catheters. These catheters are deficient because they require the use of an extension guide to reduce the enlargement during introduction of the catheter. The guide should be stiff enough to keep the catheter tightly stretched, without the enlargement, which compromises flexibility of the catheter and may cause a trauma during introduction.

It is an object of the present invention to provide a permanent self-retaining catheter, which would allow for draining the bladder to fuller extent compared to the balloon catheters.

Another object of the invention is to provide a permanent catheter having a retention means, the catheter being easy to introduce into a cavity to be drained without using a guide.

Still another object of the invention is to provide a relatively simple and low-cost catheter.

We have discovered a permanent self-retaining catheter, having a substantially cylindrical conduit open at the proximal end, characterized by the fact that it has at its distal end an elastic peripheral wall, which has axially a cylindrical shape in the non-use condition, merging substantially with the conduit shape, and at least one axial slit in the zone of said elastic wall, and by the fact that it is provided with a means to deform said wall.

The invention will be better understood from the accompanying drawings, which illustrate schematic examples, not to scale, showing various embodiments of a permanent catheter according to the present invention.

Figure 1 shows a balloon catheter placed in the bladder.

Figure 2 is an elevation view of a permanent catheter showing the first embodiment in the non-use condition .

Figure 3 is a view in section by the plane of axial symmetry of the catheter of Figure 2 in the deformed condition.

Figure 4 is a general elevation view of the distal end of the catheter in place within the bladder.

Figure 5 is a view of the catheter shown in Figure 3 in section taken along line V-V perpendicularly with respect to the catheter axis, showing an embodiment of a central guide.

Figures 6 et 7 are elevation views of two other embodiments of the distal end of the permanent catheter in the non-use conditions.

Figures 8 through 13 are elevation views, partly in section by the axial plane, showing other embodiments of the proximal end of the permanent catheter according to the invention.

La Figure 14 is a view in section by a plane perpendicular with respect to the catheter axis, showing an embodiment of the conduit.

Figures 2 and 3 illustrate the first embodiment a permanent catheter according to the invention. A permanent catheter (1) is shown in Figure 2 in the non-use condition, and it is shown in Figure 3 with an enlargement in a sectional view.

The permanent catheter (1) according to the invention has a substantially cylindrical conduit (2) open at its proximal end (3) and closed at its distal end (4) by a plug (8), which is connected to the conduit (2) by any known means, e.g., by welding, cementing, or press-fitting. The wall of the conduit (2) in the vicinity of the distal end (4) has three axial slits extending in parallel with the axis of the conduit (2), which are shown at (5) and (6).

The catheter according to the invention has, inside the conduit (2), a pulling thread (7), attached to the plug (8) at the distal end (4) of the catheter and extending outside the proximal end (3) when the catheter is in the non-use condition. The pulling thread may be in the form of a substantially cylindrical thread similar to silkgut; it may be also composed of a plurality of filaments, e.g., braided or twisted together .

The plug (8) is preferably provided with an aliging guide (9), and the pulling thread may pass through the aligning guide within a small passage (30) and may be attached to the plug (8). The pulling thread may also be connected to the aligning guide over the entire length thereof.

The aligning guide (9) may be of any simple elongated configuration, and it will be understood that the aligning guide define a passage between itself and the inner surface of the conduit, and the passage may have a substantially annular cross-section. The aligning guide (9) may also be substantially cylindrical, with a diameter substantially equal to the inside diameter of the conduit (2), and in such case it is provided with axially extending grooves assuring communication between an enlargement (12) and the conduit (2), allowing fluid to flow out. It is preferred that the aligning guide be inscribable in an imaginary cone coaxial with the conduit (2) whose base is aligned with the plug (8). The aligning guide (9) is made in such a manner that it has a three-pronged star-shaped cross-sectional configuration in the plane perpendicular with respect to the axis of the imaginary cone, preferably a star-shaped configuration. It is preferred that the imaginary cone bear, along a circle (31), against the inside wall of the conduit (2) at the base of the encashment (12). Figure 5 shows a view of the aligning guide in section by a plane perpendicular with respect to the axis of the imaginary cone, with the star bearing against the conduit (2) of the permanent catheter at the base of the enlargement.

The enlargement of the permanent catheter as shown in Figure 3 is obtained by moving the distal end closer to the proximal end by applying a substantially axially directed force F to the pulling thread (7). The force F tightens the pulling thread, thus causing the distal end to move closer to the proximal end, thereby causing the enlargement (12) to form in the zone of the slits, defining three openings such as (10) and (11). The aligning guide assures alignment of the enlargement with the axis of the conduit and also

positions the openings (10) symmetrically.

The dimensions of the permanent catheter are chosen depending on the characteristics of the cavity that is being drained, on the entry opening of the cavity, and on the flow rate of the fluid being discharged. Thus, for a man, the permanent catheter for draining urine from the bladder should be between 15 and 50-mm long, with the inside diameter between 1 and 10 mm.

In the vicinity of the distal end, in the zone where the conduit has the slits, the conduit wall thickness may be slightly smaller in order to facilitate formation of the enlargement. The permanent catheter may also have the same wall thickness along the entire length thereof.

In the vicinity of the distal end, the permanent catheter has at least one slit, generally a plurality of slits, and advantageously these slits have the same length, they are all located at the same distance from the distal end, and they are equally spaced over the peripheral surface of the conduit. The slit length is chosen in such a manner that the maximum diameter of the enlargement range between 1.5 and 10 times the outside diameter of the conduit. It is preferred that the enlargement extends diametrically up to an imaginary axial cylinder whose diameter ranges from 3 to 8 times the outside diameter of the substantially cylindrical conduit of the permanent catheter. The length of the slits is preferably chosen in such a manner that the total cross-sectional area of the openings defined by the enlargement is larger than the internal scross-section area of the conduit.

The distal end of the permanent catheter according to the invention has a shape similar to that of Malécot catheter when in the enlarged condition.

Figure 4 shows the permanent catheter (1) in the enlarged condition, placed within the cavity. It can be seen that the enlargement (12) bears against the wall (13) of the cavity thus retaining the catheter within the cavity.

The placement of the permanent catheter according to the invention is very easy. In point of fact, the cylindrical shape of the catheter facilitates its insertion into a biological passage. The distal end of the catheter attains the cavity to be drained, pulling at the pulling thread immediately causes formation of the enlargement and openings, and the distal end of the catheter cannot now leave the cavity prematurely. Then the proximal end of the pulling thread is held against the outside periphery of the conduit. The proximal end of the catheter is

connected to a discharge tube for removal of the drained biological fluid, and the tube may be press-fitted upon the proximal end of the catheter, binding the proximal end of the pulling thread. In this manner, the pulling thread is kept tight, and the catheter remains in the enlarged condition.

The catheter removal is very easy. When the evacuation tube is disengaged, the pulling thread is released, the permanent catheter takes its no-use condition shape, i.e., its outside profile becomes substantially cylindrical, thus allowing its withdrawal.

The present invention also covers embodiments of the permanent catheter that can be created by a man skilled in the art. The embodiments that will be described below are given as non-limiting examples.

The distal end (4) of the permanent catheter (1), as shown in Figure 6, may have axial slits (5, 6), which are inclined with respect to the axis of the catheter at an angle between 0 and 40°. The catheter end in the enlarged condition is then similar to the twisted Malécot catheter.

The distal end (4) of the permanent catheter, as shown in Figure 7, may have one, or a plurality of elongated openings 14. The general configuration of the openings is not important.

Replacing the pulling thread by a rod, e.g., a semi-rigid rod, which may be made by injection integrally with the plug is also within the scope of the invention. The rod imparts substantial stiffness to the catheter, facilitating its placement. Thus the rod can function as a permanent guide for catheters having very thin walls, impacting high flexibility to the catheter.

The pulling thread may also be replaced by a small tube, which will allow for enabling a flow through the distal end of the catheter through a plug port. This tube could be used for injecting a flushing solution or a medicated solution into the cavity being drained simultaneously with the draining.

Figure 8 shows the proximal end (3) of the permanent catheter (1) according to the invention. This end has a cut (15), which may extend along the generatrix of the conduit (2). The proximal end of the pulling thread is inserted between the edges of the cut (15), which binds the pulling thread after the catheter has been set to the enlarged condition by pulling at the thread. The thread may have a retainer device (16), which can be made as a simple knot, to prevent the thread from sliding in the cut.

Figure 9 shows the proximal end (3) of the permanent catheter (1) that has a projection (17) for supporting a loop or a ring (18) located at the proximal end of the pulling thread (7) when the catheter is in the enlarged condition.

Figure 10 shows the proximal end (3) of the permanent catheter (1) having two projections (19) and (20) for engaging a bar (21) attached to the proximal end of the pulling thread (7), positioned behind the projections when the catheter is in the enlarged condition.

The permanent catheter according to the invention may be provided, for example, near its proximal end with a rigid or semi-rigid coupling, attached to the conduit, e.g., by cementing. This coupling can facilitate the hookup of the catheter to a tube for removal of the biological fluid being drained.

Figure 11 shows the proximal end of the permanent catheter according to the invention. This end has a connector (29), which is press-fitted, the connector (29) being preferably made of a rigid or semi-rigid material to facilitate the connection of the catheter to the tube, the pulling thread (7) being kept tight by friction between the connector (29) and the internal surface of the conduit (2).

The permanent catheter may have its proximal end divided into two conduits, defining a Y-shaped configuration, with the biological fluid being drained flowing through one of the conduits and the pulling thread passing through the other conduit.

Preferably, as shown in Figure 12, the permanent catheter has a Y-shaped connector (26) at its proximal end. The drained fluid flows through a conduit (23), and the pulling thread (7) passes through a conduit (24). The conduit (24) is preferably provided with a stopper (25), which is made, e.g., of a flexible and elastic material, through which the pulling thread passes, thus holding the thread by friction.

Figure 13 shows an embodiment of the stopper (25). This stopper (25) is composed of two substantially semi-cylindrical parts mating with their planar rectangular faces (27). The pulling thread (7) passes between the planar faces (27), and the pinching through the wall of the conduit (2) in the direction of arrows F positioned in the plane of the planar faces (27) results in a clearance defined between the planar faces, allowing the pulling thread to move. When the pinching action is released, the pulling thread (7)remains jammed between the planar faces. The pulling thread preferably has a knot or a small bead (28) attached to it, preventing the thread from sliding and the enlargement of the catheter from being lost.

The knot or the bead has dimensions such that it cannot pass trough the clearance when the thread (7) is being pulled.

The permanent catheter may have an opening located at its distal end in the axis of the conduit. Such catheter may preferably have at least two pulling threads attached to the conduit wall at the distal end.

The permanent catheter according to the invention, which is provided with a plurality of pulling threads, may have auxiliary passages within the conduit wall for passage of the threads. The permanent catheter having the conduit cross-section shown in Figure 1 has two pulling threads (7) that pass through auxiliary passages (22).

The permanent catheter according to the invention may have division marks,. e.g. in centimeters along the generatrix of the conduit.

The permanent catheter may have two reference marks on the pulling thread corresponding to the non-use condition and enlarged condition of the catheter. The reference marks are used as a guide for the medical professional during the placement operation and allow him/her to make sure during the removal that the catheter is not enlarged.

It will be understood that two or more embodiments may be combined without going beyond the scope of the invention.

The permanent catheter according to the invention may be made of various materials that are both flexible and elastic, opaque or not, which may be coated with a material compatible with the body or with the biological fluids that can be discharged into the interior.

The following materials can be used for the conduit and also for the connector and coupling: natural or synthetic polyurethane rubbers, polyvinyl chloride; it is, however, preferred that the use be made of silicone elastomers, which are both flexible, elastic, tight for fluids, and biocompatible. In addition, silicone elastomers allow for dry thermal sterilizing of the catheter. The semi-rigid couplings may be made of polyethylene.

The pulling thread may be made of natural or synthetic textile fiber, the pulling rod may be made of polyethylene, polyvinyl chloride or polytetrafluoroethylene.

The permanent catheter according to the invention may contain a radiologically opaque material introduced either in full in a uniform fashion or locally. For example a filament-like radiologically opaque member may be embedded in the catheter wall so as to allow

the radiographic images to have a reference mark. It is possible in this manner, to introduce., e.g., in the plug, a grain of radiologically opaque material to assure an easy reference for the position of the distal end, for example, during the placement of the permanent catheter.

As the radiologically opaque materials, compounds containing heavy metals such as barium and bismuth can be used.

In order to avoid deposits because of a prolonged contact with biological fluids, more specifically, with urine, it is especially preferred to varnish the internal and/or external surfaces of the catheter including the pulling thread with a thin layer of an organosilicon elastomer, more specifically, of the kind described in the published French patent specification No. 2 126 573.

The permanent catheter according to the invention is easy to manufacture. Actually, its is easy to extrude the conduit and make the slits by blades after vulcanization on the one hand, and on the other hand, the plug may be easily made by molding, with the pulling thread then attached to it by cementing. The plug is then assembled by cementing or by press-fitting with the distal end of the conduit, with the pulling thread being caused to slide within the conduit. The plug, the aligning guide and the rod that is used for pulling may be fabricated simultaneously, for example by injection molding.

The permanent catheter according to the invention has numerous advantages, and, more specifically, it allows for complete draining of the cavity in which it is inserted. In effect, if Figures 1 and 4, which show the prior art permanent catheter and that according to the invention placed in the bladder are compared, it can be seen that with the use of the permanent catheter according to invention, the openings that let the urine to drain are located at the wall of the bladder, thus assuring complete evacuation of the bladder, which is not the case with the catheter shown in Figure 1.

Another advantage of the permanent catheter according to the invention is the fact that it can be made easily and at a low cost. Unlike the balloon catheters, it does not require sealed assembly of the various component part, and there is no need to assure perfect tightness between the plug and the conduit.

The permanent catheter according to the invention is self-retaining, in other words, it retains itself within the bladder while having certain flexibility of the enlargement, which absorbs the effect of an accidental pulling at the conduit.

The permanent catheter according to the invention also has an advantage of facilitating the operation of its placement into a cavity. In effect, it does not require the use of an extension guide for its placement because it is substantially cylindrical from the distal end to the proximal end, nor does it require the use of auxiliary materials for forming an enlargement at the distal end.

The permanent catheters having a small tube that opens the distal end have an advantage of allowing for draining, e.g., with simultaneous flushing.

The permanent catheter according to the invention is well fit for draining of a biological cavity. It is preferably used for continuous draining of a cavity communicating with a place outside the body through a natural biological or artificial passage. In effect, the permanent catheter according to the invention is especially helpful in draining urine from the bladder, with the catheter being introduced through the urethra until the zone of the conduit that has the slits is entirely received within the bladder.

CLAIMS

1) A permanent self-retaining catheter, comprising a substantially cylindrical conduit open at the proximal end, characterized by the fact that it comprises at its distal end a peripheral elastic wall, which has an axially cylindrical shape in the non-use condition, merging substantially with the conduit shape, and at least one axial slit in said peripheral, and by the fact that it has means to deform said wall by moving the distal end closer to the proximal end.

2) The catheter of claim 1, characterized by the fact that said means is comprised of at least one pulling thread located within said conduit, said pulling thread having one end that is attached to said conduit near the distal end, the other end extending outside said conduit at the proximal end.

3) The catheter of one of claims 1 or 2, characterized by the fact that the pulling thread is a tube open at the distal end of the catheter.

4) The catheter of one of claims 1, 2 or 3, characterized by the fact that it comprises means for holding the elastic wall in the deformed position.

5) The catheter of any of the foregoing claims, characterize by the fact that said means allows for attaching the proximal end of the pulling thread to the proximal end of the conduit when the catheter is in the deformed state.

6) The catheter of any of claims 4 or 5, characterized by the fact that the means that allows for attaching the pulling thread to the proximal end is made as a cut in said proximal end of said conduit.

7) The catheter of any of claims 4 or 5, characterized by the fact that the means that allows for attaching the pulling thread to the proximal end is made as a projection with which engages a loop integral with the proximal end of the pulling thread.

8) The catheter of any of claims 4 or 5, characterized by the fact that the means that allows for attaching the pulling thread is made as two adjacent projections behind which a bar connected to the proximal end of the pulling thread is engaged.

9) The catheter of any of claims 4 or 5, characterized by the fact that said means is formed by a connector or stopper, said connector or stopper allowing for securing the proximal end of the pulling thread.

10) The catheter of one of claim 9, characterized by the fact that the pulling thread is secured by friction between the connector or stopper and the conduit.

11) The catheter of one of claim 9, characterized by the fact that the pulling thread is secured by friction between two parts of the stopper, the stopper being made of two axially parting component parts.

12) The catheter of any of the foregoing claims, characterized by the fact that the deformed elastic wall has an external shape of an enlargement that merges gradually with the flexible conduit.

13) The catheter of any of the foregoing claims, characterized by the fact that said enlargement is similar to that of Malécot nephrostomy catheter.

14) The catheter of any of the foregoing claims, characterized by the fact that the axial slit in the zone of the elastic wall is inclined with respect to the axis of the conduit at angle ranging from 0 to 40 degrees.

15) The catheter of any of the foregoing claims, characterized by the fact that it comprises means for aligning the enlargement with respect to the conduit.

16) The catheter of any of claims 1 or 2 or 4 through 15, characterized by the fact that it is closed at the distal end along the conduit axis.

17) The catheter of any of the foregoing claims, characterized by the fact that it is made of a silicone elastomer.

18) The catheter of any of the foregoing claims, characterized by the fact that it is varnished internally and/or externally.

19) The catheter of any of the foregoing claims, characterized by the fact that it comprises at least one radiologically opaque element.